

REMARKS

Claims 1, 2, 4, 7, 16, 18, and 24-26 are pending. No claims have been added, canceled, or amended herein.

In view of the arguments set forth below, applicants maintain that the Examiner's outstanding rejection has been overcome and respectfully requests that the Examiner reconsider and withdraw same.

Rejection Under 35 U.S.C. §103(a)

The Examiner rejected claims 1, 2, 4, 7, 16, 18 and 24-26 under 35 U.S.C. §103(a) as allegedly unpatentable over Hsueh in view of McCoy, of record.

In response to the Examiner's rejection, applicants respectfully traverse, and maintain that the Examiner has failed to establish a *prima facie* case of obviousness. In support of this position, applicants herein incorporate by reference their remarks made in the June 4, 2004 Communication, and make the following additional remarks.

The instant claims provide, in relevant part, a nucleic acid which encodes a soluble polypeptide comprising an extracellular domain of a gonadotropin receptor and thioredoxin. The claims also provide the encoded polypeptide.

Hsueh teaches a fusion protein comprising the extracellular domain of, e.g., the LH receptor, wherein the extracellular domain of the receptor is linked to a *transmembrane anchor protein*.

McCoy teaches that heterologous genes encoding *small* peptides may be expressed in bacteria as fusion proteins comprising a "thioredoxin-like" protein, which fusion proteins are both soluble and stable relative to the peptides alone.

To establish a *prima facie* case of obviousness, the Examiner must demonstrate three things with respect to each claim. First, the cited references, when combined, teach or suggest every element of the claim. Second, one of ordinary skill would have been motivated to combine the teachings of the cited references at the time of the invention. And third, there would have been a reasonable expectation that the claimed invention would succeed.

Here, the references cited against the rejected claims fail to support a *prima facie* case of obviousness. Specifically, the cited references fail to provide a reasonable expectation of success.

Again, this invention provides a soluble fusion protein comprising, in relevant part, the extracellular domain of a gonadotropin receptor. This extracellular domain is capable of binding to gonadotropin. The soluble fusion protein does not contain any of the gonadotropin receptor's transmembrane or intracellular domains.

Prior to the instant invention, there existed uncertainty in the art as to whether a functional extracellular domain of a gonadotropin receptor could be expressed. One reason is that, at that time, one skilled in the art could not have known whether the transmembrane region of the receptor was required for gonadotropin binding to occur, or the extracellular domain of the receptor alone was sufficient to permit such binding. It was applicants' invention which established that the extracellular domain of the receptor is alone sufficient to permit ligand binding. Therefore, despite the teachings of the cited references, one skilled in the art could not have reasonably expected that the claimed gonadotropin receptor thioredoxin fusion protein would succeed absent

Applicants: Leslie Lobel and Joyce Lustbader
Serial No.: 09/804,626
Filed: March 9, 2001
Page 4

experimentation, because of the uncertainty in the art concerning the receptor domains necessary for ligand binding.

The Examiner has failed to cite any reference teaching or suggesting that, prior to applicants' invention, the above uncertainty in the art had been resolved. Accordingly, the Examiner has taken an impermissible leap in maintaining that the subject invention would have been obvious. Applicants maintain that the Examiner's rejection is thus improper and respectfully request that it be withdrawn.

In view of the above remarks, applicants maintain that claims 1, 2, 4, 7, 16, 18 and 24-26 satisfy the requirements of 35 U.S.C. §103(a).

Summary

In view of the remarks made herein, applicants maintain that the claims pending in this application are in condition for allowance. Accordingly, allowance is respectfully requested.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone them at the number provided below.

Applicants: Leslie Lobel and Joyce Lustbader
Serial No.: 09/804,626
Filed: March 9, 2001
Page 5

No fee, other than the enclosed \$455.00 fee, is deemed necessary in connection with the filing of this Communication. However, if any additional fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,

A handwritten signature in dark ink, appearing to be 'John P. White', written over a horizontal line.

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